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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,888	03/06/2002	Minoru Takebe	211A 3161 PCT	2747

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EXAMINER	
LI, QIAN JANICE	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,888	TAKEBE ET AL.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-13 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/28/05 has been entered.

The amendment submitted 6/30/05 has been entered. Claims 1, 3, 4, 9, 10 have been amended. Claims 1-7, 9-13, 15 are pending and under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of Claims 1-7, 9-13, and 15 under 35 U.S.C. 112 first paragraph for new matter is withdrawn in view of claim amendment.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and following.

The claims are drawn to a somatic stem cell-augumenting material, which broadly encompassing augmenting any feature of any somatic stem/progenitor cells of any tissue/organ in the body.

In view of the guidance provided, the specification teaches exposing rats to radiation followed by bone marrow transplantation (BMT), and then feeding different groups of rats with regular food or food containing isoflavone aglycone. The specification teaches that rats with added isoflavone aglycone, particularly higher doses, would have higher numbers of spleen colonies post-BMT (figures 4, 7, 11). However, the specification fails to teach whether the increased spleen cell colonies are the results of direct effect of the concentrated isoflavone aglycone on hematopoietic stem cells, and it fails to show any direct effect on the characteristics of any type of somatic stem cell itself either in vitro or in vivo. Considering different types of somatic stem cells, such as epithelial stem cells, liver stem cells, and kidney stem cells, differ significantly in structural characteristics, proliferative potential, divergent biological function, and conditions under which their characteristics would be augmented, the instant disclosure is insufficient to support the full scope of the claims. For example, pluripotent hematopoietic stem cells are active proliferating cells supporting multilineage development whereas nerve stem cells have only been identified until recently, and successful culture could only be done in oncogene transformed cell lines (*Villa et al*, Biomed Pharmacother 2001;55:91-5). Since the self-renew potential and cultivation

condition for the two types of stem cells differ significantly, one cannot extrapolate the teaching of the specification to apply such for augmenting any feature of any somatic stem cell.

In view of the state of the art concerning the function of isoflavone aglycones, it is known that isoflavone aglycones have health-promoting effect in general such as taught by *Kelly et al* (US 6,642,212), and *Takebe et al* (US 6045819 and 6303161). However, it is unknown and the specification fails to teach whether the increased spleen cell colonies are the direct effect on stem cells, or indirect effects on other *in vivo* factors such as cytokines, cell growth factors, or resulting from promoting general health conditions. In fact, figure 7 shows that spleen colonies were less compared to the control groups in one of the two experimental groups (experimental group 3) ingested the claimed material. Accordingly, the specification fails to provide an enabling disclosure for what is now claimed.

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation.

It is noted since the specification does illustrate the claimed material promoted spleen cell colony formation after hematopoietic cell transplant post radiation, if the preamble is limited to this finding, this rejection may be obviated.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record.

Additionally, Claims 7, 12, 15 are vague and indefinite because of the claim recitation, "said material produced by hydrolysis of isoflavone aglycone is further concentrated". These claims depend from claim 1, which is now drawn to a material comprising *concentrated* isoflavone aglycone, it is unclear the further concentration step still applies to the concentrated isoflavone aglycone, and thus the metes and bounds of the claims are uncertain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The prior rejection of Claims 1-7, 9-13, and 15 under 35 U.S.C. 102(b) as being anticipated by *Takebe et al* (USP 5,885,632), is withdrawn in view of the amendment and because the cited patent does not teach a concentrated isoflavone aglycone.

The prior rejection of Claims 1-7, 9-13, and 15 under 35 U.S.C. 102(b) as being anticipated by *Takebe et al* (USP 6,045,819), is withdrawn in view of the amendment and because the cited patent does not teach a concentrated isoflavone aglycone.

The prior rejection of Claims 1-7, 9-13, and 15 under 35 U.S.C. 102(e) as being anticipated by *Takebe et al* (USP 6,303,161), is reinstated upon further consideration.

In 6/29/05 response, the applicant pointed to tables 4 and 5 of the cited patent, and argued, "neither table discloses that the isoflavone aglycone would be comprised of 70 wt% daizein".

In response, although the '161 patent does not contain a table as does the table 2 of instant specification showing a component analysis of the concentrated product, a careful comparison would find the process of making the product appears to be identical in the cited patent and the present application (e.g. figure 1 is identical compared to instant figure 1). The cited patent also teach the product can be concentrated (e.g. abstract). Since a product produced by the same process should possesses the same daizein (daidzein) content in the absence of the evidence to the contrary, *Takebe et al* anticipate instant claims.

Applicant is reminded the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the

burden is upon the applicant to prove that the prior art products do not necessarily or inherently possess characteristics of claimed product, which requires factual evidence demonstrating that actual, unobvious differences exist (or that the claimed products are functionally different than those taught by the prior art) and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPBI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922, 1923 (BPAI 1989).

Applicant is reminded that a terminal disclaimer cannot obviate a 102(e) rejection. A 35 U.S.C. 102(e) rejection can be overcome by showing the reference is describing applicant's own work (See MPEP 2136.05); or showing inventions were commonly owned at time of applicant's invention.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Kelly et al* (USP 6,642,212).

Kelly et al teach a material comprising isoflavone aglycone (abstract), wherein the aqueous extract is further concentrated (column 12, line 57), wherein said isoflavone aglycone is comprised of 95% daidzein (genistein:diadzein=1:19, claim 13). Thus, *Kelly et al* anticipate instant claims.

The prior provisional rejection of Claims 1-7, 9-13, 15 under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/284,935, is withdrawn because the cited application is now abandoned.

Claims 1-7, 9-13, and 15 stand rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. US patent 6,303,161 anticipates instant claims but has a different inventive entity, and thus it is unclear who is the real inventor.

Applicant is reminded that a terminal disclaimer cannot obviate a 102(f) rejection. A 35 U.S.C. 102(e) rejection can be overcome by showing the reference is describing applicant's own work (See MPEP 2136.05); or showing inventions were commonly owned at time of applicant's invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **Victor Barlow**, whose telephone number is (571) 272-0506.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
December 7, 2005